

## REMARKS

### Claim Rejections – 35 USC §102 and §103

Claims 2, 3, 15, 28-31, 35, 38, 46 and 50 have been rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,281,262 to Shikinami. Additionally, claims 42-44 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Shikinami in view of U.S. Patent No. 3,867,728 to Stubstad, claims 36, 57, 58 and 80-88 have been rejected as being unpatentable over Shikinami, claims 39-41 have been rejected as being unpatentable over Shikinami in view of U.S. Patent No. 6,491,724 to Ferree, and claims 59-64, 67, 70 and 79 have been rejected as being unpatentable over Shikinami in view of Stubstad and Ferree.

### Claim Amendments

Claims 84 and 85 have been rewritten in independent form. Additionally, dependent claim 50 has been amended to improve its forms and new dependent claim 104 has been added.

### Arguments in Support of Patentability

The Applicant notes that “an invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claim.” Richardson v. Suzuki Motor Co. Ltd., 9 USPQ.2d 1913, 1920 (Fed. Cir. 1989). Additionally, the Office Action asserts that “[w]ith regard to the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Shikinami”. (See page 3 of the Office Action). However, as set forth in detail below, independent claims 28 and 42 recite structural features that are submitted to clearly distinguish over Shikinami.

### Independent Claim 28 and Dependent Claims 2-4, 15, 29-36, 38-41, 46-58 and 80-88

Independent claim 28 has been rejected as being anticipated by Shikinami. Specifically, the Office Action asserts that the device illustrated in Figures 24 and 25 of Shikinami discloses an expandable spacer comprising “an elongate, cylindrical body composed of a shape memory polymeric material and comprising a first bearing surface and an opposite second bearing surface and a peripheral sidewall positioned therebetween and defining an interior cavity, wherein the

peripheral wall comprises at least one opening extending into the interior cavity, the body can be provided in a first configuration wherein the body expands to a second configuration, the second portion having a greater area than the first portion, wherein the first configuration has a first width and the second configuration has a second width (sic), wherein the second width can be greater than the first width". (See pages 2 and 3 of the Office Action).

Independent claim 28 recites, among other elements and features, "a body composed of a shape memory polymeric material and comprising a peripheral sidewall defining an interior cavity and vertebral bearing surfaces at opposite ends of the peripheral sidewall", the body having "a first configuration . . . wherein said body upon absorption of thermal energy expands to a second configuration", "wherein the peripheral sidewall in the first configuration has a first lateral dimension and the vertebral bearing surfaces each define a first bearing surface area", "wherein said body upon absorption of thermal energy expands to a second configuration" and "wherein the peripheral sidewall in the second configuration has a second lateral dimension greater than the first lateral dimension and the vertebral bearing surfaces each define a second bearing surface area significantly greater than the first bearing surface area".

As an initial matter, the device illustrated in Figures 24 and 25 of Shikinami does not comprise an expandable spacer for implantation between opposing endplates of adjacent vertebrae, and the device likewise does not include a peripheral sidewall defining vertebral bearing surfaces at opposite ends thereof, as recited in independent claim 28. To the contrary, the device illustrated in Figures 24 and 25 comprises a vascular stent initially positioned within a blood vessel 110 while in an original shape 12, and which is transitioned from the original shape 12 to the expanded shape 12a within the blood vessel 110 to prevent vascular reconstruction. While the stent includes a peripheral sidewall, the sidewall does not define vertebral bearing surfaces at opposite ends thereof.

Additionally, although the expanded shape 12a of the stent arguably has a second lateral dimension that is greater than a first lateral dimension defined by the original shape 12 of the stent, the expanded shape 12a does not have vertebral bearing surfaces at opposite ends thereof which define a second bearing surface area significantly greater than a first bearing surface area defined by the original shape 12 of the stent. As clearly shown in Figures 24 and 25, while the

shape or outer profile of the sidewall is modified between the original shape 12 and the expanded shape 12a, the thickness and cross-sectional area of the sidewall remain unchanged. As a result, the surface area defined by the ends of the stent sidewall when expanded from the original shape 12 to the expanded shape 12a remains unchanged. This is clearly illustrated in Figures 24 and 25 of Shikinami wherein the cross-section area of the implant, and correspondingly the surface area defined by the ends of the device, remains unchanged. The Applicant notes that the perimeter of the device (i.e., the perimetrical length of the device wall) does not change between the original shape 12 and the expanded shape 12a of the device, but instead remains constant. Accordingly, in order for the surface area defined by the end surfaces of the device to increase, the thickness of the device wall must increase. As illustrated in Figures 24 and 25, the thickness of the device wall remains constant. Therefore, the surface area defined by the end surfaces of the device also remains constant.

Accordingly, the surface area defined by the ends of the stent sidewall when in the expanded shape 12a is not significantly greater than the surface area defined by the ends of the stent sidewall when in the original shape 12, as recited in independent claim 28. To the contrary, the surface area defined by the ends of the stent sidewall remains unchanged, and the surface area defined by the ends of the stent sidewall when in the original shape 12 is equal to the surface area defined by the ends of the stent sidewall when in the expanded shape 12a. In other words, although the overall shape or outer profile of the stent sidewall expands and changes shape between the original and expanded shapes 12, 12a, such change in shape/outer profile does not result in a greater surface area defined by the end surfaces of the stent. Although the expanded configuration of the stent has an expanded shape 12a that appears to have a greater width compared to that of the original shape 12, the surface area defined by the end surfaces of the stent in the original and expanded shapes 12, 12a remains the same.

Since Shikinami fails to disclose or suggest each of the elements and features recited in independent claim 28, the Applicant submits that independent claim 28 is not anticipated by Shikinami, and withdrawal of the rejection of independent claim 28 is respectfully requested.

Claims 2-4, 15, 29-36, 38-41, 46-58 and 80-88 depend either directly or indirectly from independent claim 28, and are submitted to be patentable for at least the reasons supporting the

patentability of independent base claim 28. However, the Applicant notes that the claims depending from independent claim 28 are patentable for other reasons in addition to those supporting the patentability of independent claim 28. For example, claim 50 has been amended to recite that “the first configuration of the body comprises a compressed flattened configuration, and wherein the second configuration of the body comprises an expanded cylindrical configuration”. However, none of the device embodiments illustrated Shikinami disclose or suggest an expandable spacer having a compressed flattened configuration and an expanded cylindrical configuration.

**Independent Claim 42 and Dependent Claims 43, 44, 59-61, 63-72, 77-79 and 104**

Independent claim 42 has been rejected as being unpatentable over Shikinami in view of Stubstad. Specifically, the Office Action admits that “Shikinami discloses the claimed invention except for a peripheral sidewall that has two thicknesses in a cross section area”, but asserts that “Stubstad discloses a spacer that has sidewalls (44) having two dimensions (see Figs. 8-9). Having sidewalls with varying thicknesses help to assist the spacer in maintaining the intervertebral space with respect to varying compressive loads. It would have been obvious . . . to construct the device of Shikinami (US Patent Number 6,281,262) having the varying wall thickness of Stubstad ‘728 so that the compressive forces of the intervertebral areas may be fully supported”. (See page 4 of the Office Action).

Independent claim 42 recites, among other elements and features, “a body composed of a shape memory polymeric material and comprising a peripheral sidewall defining an interior cavity and vertebral bearing surfaces at opposite ends of the peripheral sidewall”, the body having “a first configuration . . . wherein said body upon absorption of thermal energy expands to a second configuration”, “wherein the peripheral sidewall in the first configuration has a first lateral dimension and a first sidewall thickness defining a first cross-sectional area”, and “wherein the peripheral sidewall in the second configuration has a second lateral dimension greater than the first lateral dimension and a second sidewall thickness greater than the first sidewall thickness, the second sidewall thickness defining a second cross-sectional area significantly greater than the first cross-sectional area”.

As an initial matter, the device illustrated in Figures 24 and 25 of Shikinami does not comprise an expandable spacer for implantation between opposing endplates of adjacent vertebrae, and the device likewise does not include a peripheral sidewall defining vertebral bearing surfaces at opposite ends of the peripheral sidewall, as recited in independent claim 42. Additionally, although the expanded shape 12a of the stent illustrated in Figures 24 and 25 arguably has a second lateral dimension that is greater than a first lateral dimension defined by the original shape 12 of the stent, the expanded shape 12a does not have a peripheral sidewall having a sidewall thickness defining a cross-sectional area which is significantly greater than a sidewall thickness and cross-sectional area defined by the original shape 12 of the stent. Indeed, as shown in Figures 24 and 25, while the sidewall of the stent changes shape between original shape 12 and the expanded shape 12a, the thickness and cross-sectional area of the stent sidewall remain unchanged. In other words, although the overall shape or outer profile of the stent sidewall changes between the original and expanded shapes 12, 12a, such change in shape/outer profile does not result in a greater thickness of the stent sidewall or a greater cross-sectional area defined by the thickness of the stent sidewall.

As indicated above, the Office Action asserts that “Stubstad discloses a spacer that has sidewalls (44) having two dimensions (see Figs. 8-9), and that “[i]t would have been obvious . . . to construct the device of Shikinami (US Patent Number 6,281,262) having the varying wall thickness of Stubstaud ‘728 so that the compressive forces of the intervertebral areas may be fully supported”. (See page 4 of the Office Action). The Applicant respectfully disagrees with this assertion. Figure 8 of Stubstaud discloses an implants 15B having a posterior wall 44 and reinforcement members 45 that “hold the core 15B in its kidney-like shape”. (See column 10, lines 16-19). Similarly, Figure 9 of Stubstaud discloses an implants 15C having a posterior wall 44 and a reinforcing member 46 that holds the core 15C in its predetermined shape. (See column 10, lines 24-26). The implant embodiments 15B and 15C are “kept from deforming into a rounded shape” via the reinforcing members 45 and 46. (See column 10, lines 12-15; emphasis added).

As should be apparent, the implant embodiments 15B and 15C of Stubstaud are not in any way expandable, and do not have “a first configuration . . . wherein said body upon

absorption of thermal energy expands to a second configuration”, as recited in independent claim 42. To the contrary, the implant embodiments 15B and 15C are non-expandable and clearly do not change shape from a first configuration to a second configuration upon absorption of thermal energy. Indeed, Stubstaud specifically disclose that the implant embodiments 15B and 15C are “kept from deforming into a rounded shape” via the reinforcing members 45 and 46. (See column 10, lines 12-15; emphasis added). Accordingly, Stubstaud actually teaches directly away from providing an expandable spacer that has “a first configuration” that “expands to a second configuration” upon absorption of thermal energy, as recited in independent claim 42.

Furthermore, even assuming arguendo that the peripheral sidewall of the implant embodiments 15B, 15C have a varying thickness, as indicated above, the implant embodiments 15B and 15C are non-expandable and do not change from a first configuration to a second configuration upon absorption of thermal energy, with the first configuration having “a first lateral dimension and a first sidewall thickness defining a first cross-sectional area”, and with the second configuration having “a second lateral dimension greater than the first lateral dimension and a second sidewall thickness greater than the first sidewall thickness, the second sidewall thickness defining a second cross-sectional area significantly greater than the first cross-sectional area”. Indeed, the lateral dimension, the cross-sectional area, and the thickness of the peripheral sidewall of the implant embodiments 15B, 15C are all constant and non-changing. Additionally, even assuming arguendo that the peripheral sidewall has a varying thickness, such variation is present in a single configuration of the implant, and the peripheral sidewall does not increase in thickness from a first configuration to an expanded second configuration. Furthermore, the cross-sectional area of the peripheral sidewall and the lateral dimensions of the peripheral sidewall do not in any way change from a first configuration to an expanded second configuration. Instead, the cross-sectional area and the lateral dimensions of the peripheral sidewall are constant and non-changing. Indeed, the Office Action does not even address how the peripheral sidewall of the implant embodiments 15B, 15C of Stubstaud could in any way be construed as having “a second cross-sectional area significantly greater than a first cross-sectional area”, as recited in independent claim 42. As should be readily apparent, the cross-

sectional area of the peripheral sidewall is constant and does not increase between a first configuration and an expanded second configuration.

Since Shikinami and Stubstad fail to disclose or suggest each of the elements and features recited in independent claim 42, the Applicant submits that independent claim 42 is patentable over these references, and withdrawal of the rejection of independent claim 42 is respectfully requested.

Claims 43, 44, 59-61, 63-72, 77-79 and 104 depend either directly or indirectly from independent claim 42 and are submitted to be patentable for at least the reasons supporting the patentability of independent base claim 42. However, the Applicant notes that the claims depending from independent claim 42 are patentable for other reasons in addition to those supporting the patentability of independent claim 42.

For example, claim 43 recites that “the body is provided in an original configuration having an original cross-sectional area that is greater than the first cross-sectional area”, and claim 44 further recites that “the original cross-sectional area is greater than the second cross-sectional area”. As indicated above with regard to independent claim 42, the cross-sectional area defined by the peripheral sidewall of the Stubstad is constant and does not in any way change from a first configuration to an expanded second configuration, much less from an original configuration having “an original cross-sectional area that is greater than the first cross-sectional area” defined by a first implant configuration, or an original cross-sectional area that is “greater than the second cross-sectional area” defined by a second expanded configuration. Instead, the cross-sectional area of the peripheral sidewall is constant and non-changing. Moreover, the Applicant notes that the Office Action does not even address how the peripheral sidewall of the implant embodiments 15B, 15C of Stubstaud could in any way be construed as having an original configuration with “an original cross-sectional area that is greater than the first cross-sectional area” defined by a first implant configuration, or an original cross-sectional area that is “greater than the second cross-sectional area” defined by a second expanded configuration. Accordingly, a *prima facie* case of obviousness has not been established with regard to claims 43 and 44.

Additionally, claim 104 has been added which recites subject matter similar to that recited in dependent claim 50. Specifically, claim 104 recites that “the first configuration of the body comprises a compressed flattened configuration, and wherein the second configuration of the body comprises an expanded cylindrical configuration”. However, as indicated above with regard to claim 50, none of the device embodiments illustrated Shikinami disclose or suggest an expandable spacer having a compressed flattened configuration and an expanded cylindrical configuration.

#### **Rewritten Independent Claim 84**

The Applicant has rewritten claim 84 in independent form. Claim 84 has been rejected as being unpatentable over Shikinami. Specifically, the Office Action admits that that Shikinami does not disclose the use of “two spacers”, but nevertheless asserts that “[i]t would have been obvious . . . to construct the assembly of Shikinami with two spacers” wherein “the second expandable spacer is provided in a third configuration and sized substantially the same as the first spacer in the first configuration” and wherein “the second spacer expands to a fourth configuration and is sized differently than the first spacer in the second configuration”. (See pages 4-5 of the Office Action). The Applicant submits that the grounds of rejections set forth in the Office Action with regard to claim 84 is merely a restatement of the language recited in claim 84, and does not set forth any technical reasoning or rational as to why the subject matter recited in claim 84 would have been obvious in view of Shikinami. Accordingly, a *prima facie* case of obviousness has not been established with regard to rewritten independent claim 84.

Furthermore, rewritten independent claim 84 recites each of the elements recited in independent base claim 28 which, as indicated above, is submitted to be patentable over Shikinami. Moreover, even assuming arguendo “[i]t would have been obvious . . . to construct the assembly of Shikinami with two spacers” (as asserted on page 4 of the Office Action), there is absolutely no teaching, suggestion or motivation to provide a first expandable spacer having a first configuration and an expanded second configuration, and a second expandable spacer having a third configuration sized substantially the same as the first configuration of the first spacer and wherein “the second spacer expands to a fourth configuration and is sized differently

than the first spacer in the second configuration”. Indeed, even assuming arguendo that one of ordinary skill in the art would be motivated to provide first and second expandable spacers, based on the teachings of Shikinami, one of ordinary skill in the art would not be motivated to provide the second spacer with an expanded configuration (i.e., a forth configuration) that is sized differently than an expanded configuration (i.e., a second configuration) of the first spacer. Instead, even if one of ordinary skill in the art would be motivated to provide first and second spacers, such spacers would logically be provided with identical expanded configurations. Additionally, as indicated above, the Office Action does not set forth any technical reasoning or rational as to why one of ordinary skill in the art would provide a second spacer having an expanded configuration that is sized differently from an expanded configuration of a first spacer.

For at least the reasons set forth above, the Applicant submits that rewritten independent claim 84 is patentable over Shikinami, and withdrawal of the rejection of rewritten independent claim 84 is respectfully requested.

**Rewritten Independent Claim 85 and Dependent Claims 86 and 87**

The Applicant has rewritten claim 85 in independent form. Claim 85 has been rejected as being unpatentable over Shikinami. Specifically, the Office Action admits that that Shikinami does not disclose the use of “two spacers”, but nevertheless asserts that “[i]t would have been obvious . . . to construct the assembly of Shikinami with two spacers” wherein “the second expandable spacer is provided in a third configuration and is sized differently than the first spacer in the first configuration”. (See pages 4-5 of the Office Action). The Applicant submits that the grounds of rejections set forth in the Office Action with regard to claim 85 is merely a restatement of the language recited in claim 85, and does not set forth any technical reasoning or rational as to why the subject matter recited in claim 85 would have been obvious in view of Shikinami. Accordingly, a *prima facie* case of obviousness has not been established with regard to rewritten independent claim 85.

Furthermore, rewritten independent claim 85 recites each of the elements recited in independent base claim 28 which, as indicated above, is submitted to be patentable over Shikinami. Moreover, even assuming arguendo “[i]t would have been obvious . . . to construct

the assembly of Shikinami with two spacers" (as asserted on page 4 of the Office Action), there is absolutely no teaching, suggestion or motivation to provide a first expandable spacer having a first configuration and an expanded second configuration, and a second expandable spacer that is provided in "a third configuration and sized differently than the first spacer in the first configuration". Indeed, even assuming arguendo that one of ordinary skill in the art would be motivated to provide first and second expandable spacers, based on the teachings of Shikinami, one of ordinary skill in the art would not be motivated to provide the second spacer with an initial configuration (i.e., a third configuration) that is sized differently from the initial configuration (i.e., a first configuration) of the first spacer. Instead, even if one of ordinary skill in the art would be motivated to provide first and second spacers, such spacers would logically be provided with the same initial configuration. Additionally, as indicated above, the Office Action does not set forth any technical reasoning or rational as to why one of ordinary skill in the art would provide a second spacer having an initial configuration that is sized differently from an initial configuration of a first spacer.

For at least the reasons set forth above, the Applicant submits that rewritten independent claim 85 is patentable over Shikinami, and withdrawal of the rejection of rewritten independent claim 85 is respectfully requested.

Claims 86 and 87 depend either directly or indirectly from rewritten independent claim 85 and are submitted to be patentable for at least the reasons supporting the patentability of independent base claim 85. However, the Applicant notes that the claims depending from independent claim 85 are patentable for other reasons in addition to those supporting the patentability of independent claim 85. For example, claim 87 recites that "the second spacer expands to a fourth configuration upon absorption of energy and sized differently than the first spacer in the second configuration". As indicated above with regard to rewritten independent claim 84, such features are neither disclosed nor suggested by Shikinami.

## CONCLUSION

In view of the foregoing remarks and amendments, it is respectfully submitted that the Applicant's application is in condition for allowance with pending claims 2-4, 15, 28-36, 38-44, 46-61, 63-72, 77-88 and 104.

Reconsideration of the subject application is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

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